

FEB 15 2008

Application 10/620,155
February 15, 2008 Reply to Final Rejection dated December 21, 2007

Attorney Docket P002.210

REMARKS/ARGUMENTS**I. Status of the claims**

Claims 25 - 34 were cancelled.

II. Election/Restrictions

Claims 25 -34 drawn to the non-elected invention were cancelled.

III. Examiner interview

Applicants thank Examiner Ramillano and Examiner Alexander for the telephone interview conducted on January 24, 2008. Present during the interview were Examiner Ramillano, Examiner Alexander and Applicant's representative, Sue Kalman. Applicant's representative made the following points during the phone interview:

- All pending claims are limited to extraction columns having frits less than 350 μm thick.
- Colpan does not teach frits less than 350 μm thick.
- Colpan refers to a "50 μm PE frit." One of skill in the art would recognize that in this context "50 micron" refers to pore size, not thickness.
- 50 μm thick PE material is not commercially available.
- The issue of the thickness of Colpan's frits was previously addressed in writing in October 4, 2007 amendment.

Examiner Alexander recommended the above points be put in writing in an amendment after final. Sue Kalman replied that we already put our arguments in writing in the October 4th amendment, and they were not considered. Examiner Alexander recommended that we put that in writing as well.

IV. Claim rejections under 35 U.S.C. § 112

Applicants note with appreciation the Examiner's withdrawal of the rejection of claims 1 -- 22 under 35 U.S.C. 112, second paragraph.

V. Claim rejections under 35 U.S.C. § 102.

The Examiner rejected claims 1-3, 9, 10, 14, 15 and 19-22 as allegedly anticipated by Colpan et al. (US 6,274,371, "Colpan"). Frits less than 350 microns thick are recited in claim 1 of the

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instant application and all additional claims under consideration depend from claim 1. Colpan is the sole reference relied upon by the Examiner, which the Examiner alleges teaches frits less than 350 microns thick. **The examiner does not allege that any other cited prior art teaches, suggests, or would motivate the use of frits less than 350 μm thick.** Therefore, the question of whether or not Colpan teaches thin frits is of paramount importance to the allowance of the instant application. In fact, it is the only issue remaining in the prosecution of the instant application.

A. The Examiner's arguments.

In the Final Rejection, the Examiner maintained the rejections under 35 U.S.C. § 102 and § 103 and argued that Colpan's layer (23) reads on Applicant's frit, stating that:

"[I]t appears that Colpan's layer (23) reads on applicant's frit because Colpan discloses in EXAMPLE 2, for instance, that his layer (23) is a 50 μm PE (an abbreviation known in the art for polyethylene) frit or a nylon net and is capable of holding diol-diatomaceous earth (i.e. extraction media). Thus, because Colpan discloses a frit made of either PE (polyethylene) or nylon, which is the same material as applicant uses to make his frit, Colpan's layer (23) inherently comprises the same properties recited by applicant."

The Examiner concludes the rejection as follows.

"In response to applicant's argument that Colpan does not disclose a frit that is less than 350 microns thick, examiner disagrees. Colpan discloses, which applicant also recognizes, in column 3, line 65 to column 4, line 11, a frit that is 50 μm ."

Applicants note for the record that the Examiner has asserted that Applicants recognize that Colpan discloses "a frit that is 50 μm ." The Examiner does not assert that Applicants recognize in Colpan a disclosure of a frit that is 50 μm *thick*, which is the pertinent question. As explained below, Applicants refute any implication that the "50 μm " appearing in Colpan refers to frit thickness.

B. Colpan does not expressly or inherently teach frits less than 350 micron thick.

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In the Final Rejection, the Examiner states that Colpan's layer (23) inherently comprises the same properties as the frit recited by Applicants. In this statement, the Examiner is acknowledging that Colpan does not explicitly describe, suggest or refer to a frit less than 350 microns thick. Nevertheless, the Examiner argues that such a frit is "inherently" disclosed by Colpan. According to the U.S. Court of Appeals for the Federal Circuit, and as explained in the MPEP¹, the burden of proof for rejections based on inherency lies with the Office. "In relying upon the theory of inherency, the examiner *must provide a basis in fact and/or technical reasoning* to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."² "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"³ (emphasis added)

In the present case, the extrinsic evidence does not make clear that the missing descriptive matter is necessarily present. Additionally, it would be not be recognized to be present by persons of ordinary skill. Most importantly, the burden of proof lies with the Examiner. The Examiner has not provided any technical reasoning or supporting evidence that the 50 μ m PE frit or nylon net disclosed by Colpan's is, in fact, 50 microns thick, or less than 350 microns thick. The Examiner's statement that "Colpan's layer (23) inherently comprises the same properties recited by applicant" is merely conclusory. Applicants argue herein that on the contrary, one having skill in the art would know that Colpan's PE frit is not 50 microns thick.

C. It is not reasonable that Colpan would use frits less 50 microns thick.

1. Porous polyethylene sheets are available in standard thicknesses and are identified by their pore size.

Porous polyethylene (PE) is used for a variety of applications and is commonly sold in sheet form. PE is available in several different thicknesses including 1/16th inch, 1/8th inch and 1/4th inch. One application is punching out circles to make discs, which are used as column frits.

In standard frit nomenclature, the dimension "50 μ m" refers to pore size. To further illustrate this point, Applicants include herewith web pages listing commercially available PE frits.

¹ MPEP 2112

² Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

³ In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

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This is the type of materials Colpan is describing in the phrase "50 μm PE frit". For example, the vendor Scientific Commodities (http://www.scicominc.com/porous_sheets.htm) lists porous sheets of 90 micron polypropylene, 125 micron polypropylene, 35 micron polyethylene and 70 micron polyethylene material. The sheets come in 1/16th inch, 1/8th inch and 1/4th inch thickness.

As another example, the company Science Lab.com (<http://sciencelab.com/page/S/PVAR/60-136380018>) sells Fritware Porous Polyethylene Sheets having a pore size of 70 – 90 microns and a thickness of 1/16th to 1/4th inch. On the Science Lab.com website, the fritware porous polyethylene sheets are listed under the category, "Filtration Supplies", which is consistent with the fact that Colpan's invention is a filtration column. Both of these web pages are attached as appendices. Note that the thinnest of these commercially available sheets is 1587.5 microns thick, approximately 32 times the 50 micron thickness the Examiner alleges is inherently disclosed in Colpan.

2. Polyethylene frits 50 μm thick would be exotic.

Structurally, porous PE is a rigid foam, similar to peanuts used for packing material. It consists of a network of random pores held together by polymer material. In the phrase "50 μm PE frit", Colpan could not be referring to polyethylene frits 50 μm thick because porous PE having a thickness of 50 microns is exotic. In a recent internet search, Applicants could not find any source (commercial or other) of porous polyethylene 50 micron thick. Very thin porous PE having a useable pore structure would technically, be extremely difficult to manufacture. It is difficult for Applicants to even envision a PE frit material having a thickness of 50 μm and a pore size of 20 - 100 μm . Fifty microns is less than half the diameter of a human hair. Wouldn't such a material simply fall apart? Why would Colpan use such an exotic material? Why would Colpan teach the use of a material that is not readily available? Note that the thinnest of the commercially available sheets of PE described above and in the appendices is 1/16th inch which is equivalent to 1587.5 microns thick, approximately 32 times the 50 micron thickness the Examiner alleges is inherently disclosed by Colpan.

3. Thin frits would not work in Colpan's device.

Furthermore, there would be no benefit to the use of thin frits in Colpan's filtering device, however there would be a number of disadvantages. First, very thin frits, such as 50 micron PE or nylon, if they existed would likely be structurally weak, fragile, flexible and flimsy. Thin frits

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are difficult to attach to the column making column manufacture unnecessarily complex. Thin frits can fold or pull away from the column sides or even fall out through the column outlet

Second, Colpan is using high-pressure pumping. In Example 2, Colpan discloses a peristaltic pump, while a piston (positive displacement pump labeled element 80 in the drawing) is used in Example 3. Both of these are strong pumps capable of pumping approximately 100 psi. A strong pump would deform a thin frit, possibly even pushing it out through the opening on the lower end of the column.

Third, in Example 2, Colpan discloses a 10 cm x 25 cm column filled with diatomaceous earth to a height of 5 cm. Based on this information, Applicants estimate the weight of the diatomaceous earth and liquid in the column to be at least one pound, though it could be significantly more. A PE frit 50 microns thick or nylon net less than 350 microns thick would probably not even be able to contain a pound of diatomaceous earth. Certainly, a person having skill in the art would select a strong and sturdy frit for the column in Example 2.

On the other hand, one of skill in the art would infer that the conventional frits used by Colpan are made from porous PE sheets that are thick and rigid. A frit that is rigid could be inserted into Colpan's column and held in place by friction. Colpan's frit material must be able to withstand the high pressures generated from the pumps used in Examples 2 and 3.

D. Frit pore size is very important for Colpan's device.

Colpan's device is used for filtration, the separation of liquids from solids. In a filtration device, pore size is a very important parameter whereas frit thickness is not. Colpan's drawing shows filter layer (20) which is held in place by two elements labeled with reference number 23 (referred to herein as "element 23"). Colpan gives very little information on the structure and function element 23⁴. In fact, Colpan never even uses the term "frit" to describe element 23 and never mentions the thickness of element 23

However, in the discussion of element 23, Colpan does refer to pore size. In column 3, lines 27-30, Colpan states "Where the hydrophobic separating layer 23 is arranged above separating layer 20, it is advantageous if the pore size of this separating layer is not smaller than that of underlying layer 20." Colpan makes this statement because the filtering of particles from cell lysates is performed by element 20. Consequently, it is important that the pore size of element 23 is not smaller

⁴Colpan, column 2, lines 53-54, column 3, lines 21-25, column 3, lines 27-33.

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than that used in element 20. If the pore size of element 23 was smaller than that of the filter, solids would be retained before even entering filter layer 20. Therefore, it is important for Colpan to consider the pore size of element 23 and not the thickness of element 23.

E. US Patent 5,652,141 to Henco, Colpan and Feuser discloses frit pore size.

Colpan is an inventor on Patent 5,652,141 ("Henco") which is drawn to a device and process for isolating nucleic acids from cell suspension. The device is similar to that described in Colpan in that it is also used for the preparation of nucleic acids and it contains a matrix arranged between two porous units. Henco refers to the pore size of the porous units as follows:

The device according to the invention consists of a hollow body (1) wherein the matrix (4) accommodating the cells is arranged between two porous units (2, 3). The pore size of the units 2, 3, preferably polyethylene or glass frits, must be larger than the void size of the material forming the matrix 4. The units 2, 3 have a pore size of from 50 to 100 micron, with the void size of the material forming the matrix 4 being about from 1 to 50 micron.⁵

Between two narrowly inserted units 2, 3, for example, polyethylene frits having a pore size of from 50 to 100 micron, there is situated a membrane having pores of from 5 to 10 micron in size and likewise containing silica gel...⁶

Likewise, it is possible to fill small columns with the described silica gel arranged between 2 polyethylene frits having a pore size of 35 micron. Preferably, the upper unit 2 is chosen with larger pores (70 micron).⁷

In summary, Henco teaches a device similar to the device taught by Colpan. Colpan is an inventor on both patents. Henco's device is comprised of two porous units which are preferably polyethylene or glass frits. The pore size of the porous units is described in detail in Henco, but the thickness of the porous units is never mentioned by Henco.

⁵ Henco, column 4, lines 8 – 15.

⁶ Henco, column 4, lines 29 – 33.

⁷ Henco, column 4, lines 44 – 47.

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E. The “nylon net” mentioned in Colpan is not explicitly or implicitly a frit less than 350 microns thick.

Although the Examiner does not develop this argument, it seems possible that she is asserting that the “nylon net” mentioned in example 2 of Colpan is inherently a frit of less than 350 μm . However, the examiner has clearly failed to meet her burden, as described in MPEP 2112, to provide a basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic *necessarily* flows from the teaching of Colpan. There is nothing in Colpan suggesting the structure or nature of this “nylon net.” Example 2 is merely a prophetic example, and Colpan never asserts that the inventor actually ever performed example 2. It is impossible to infer from this sparse teaching the thickness of the prophetically described “nylon net,” clearly precluding any assertion that it inherently describes a frit of less than 350 μm .

Furthermore, the instant invention is drawn to an extraction column comprised of frits less than 350 microns thick. One skilled in the art would not use the term “net” to describe a frit.

It is also instructive to consider how the term “net” is used in Henco, another patent identifying Colpan as an inventor and relating to similar technology. Henco describes the use of a “net-like membrane having a multitude of pores of from 1 to 50 micron in size.” Col. 4, lines 16-17. Far from it; a careful reading of Henco suggests that the net-like membrane is envisioned as being relatively thick. Although Henco does not provide any specific parameters for the thickness of the net-like membrane, it does identify it as matrix (4), depicted in figure 1 of Henco. Inspection of Henco’s figure 1 reveals that matrix (4) is depicted as quite thick relative to the two porous units (2, 3) retaining the matrix. There is absolutely no suggestion that the netlike membrane has a thickness of less than 350 μm . Based on this use of the term “net-like” by the Colpan inventor to identify what appears to be a thick matrix, it is impossible to infer that the use of the term net in Colpan necessarily describes a thin frit, less than 350 microns thick.

Based on the above arguments, Colpan does not teach a column having frits less than 350 microns thick. Since Colpan does not teach frits less than 350 microns thick, claim 1 is not anticipated by Colpan. Since claims 2, 3, 9, 10, 14, 15 and 19-22 all depend from claim 1 and thus further limit claim 1, claims 2, 3, 9, 10, 14, 15 and 19-22 are not anticipated by Colpan. In view of the foregoing, Applicants respectfully request withdrawal of all of the claim rejections under 35 U.S.C. § 102.

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VI. Claim rejections under 35 U.S.C. § 103.

In the Final Rejection the Examiner maintained the following rejections.

- Claim 1 as allegedly obvious over Brewer (US 6566145) in view of Colpan.
- Claims 1-6, 9-12, 14-15 and 18 - 22 as allegedly unpatentable over Hargro et al. (US 6,139,733) in view of Colpan.
- Claims 7 and 13 as allegedly unpatentable over Hargro in view of Colpan, as applied to claims 1-6, 9-12, 14-15 and 18-22 above, and further in view of Smith et al. (US Pub. No. 2004/0253687).
- Claims 8 and 16 as allegedly unpatentable over Hargro in view of Colpan as applied to claims 1-6, 9-12, 14-15 and 18-22 above, and further in view of Hunt et al. (US 2002/0110495).
- Claim 17 as allegedly unpatentable over Hargro in view of Colpan as applied to claims 1-6, 9-12, 14-15 and 18-22 above, and further in view of Halmann et al. (US 4302534).

To establish *prima facie* obviousness, the Office must provide references that, together include each element of the claimed invention. Claim 1 recites a low dead volume extraction column comprised of frits less than 350 microns thick. All claims pending in the instant application depend from claim 1, and thus include the limitation of frits less than 350 microns thick. Each of the above rejections is relying on Colpan to supply frits less than 350 μ m thick.

Applicants argued in section V, that Colpan does not teach frits less than 350 μ m thick. Therefore, the combination of Colpan and the any of the above references does not include each element of the claimed invention. Specifically, none of the references teach frits that are less than 350 microns thick. In view of the foregoing, withdrawal of all the § 103 rejections is respectfully requested.

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CONCLUSION

Applicants believe no fee is required for submission of this response, however, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 50-2852.

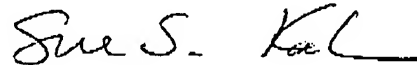
In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner seeks to maintain the rejections, Applicant requests a personal interview with the Examiner and the Examiner's supervisor, Jill Warden.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (408)267-7214.

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(408)267-7214 phone
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Respectfully submitted,



Sue S. Kalman
Reg. No. 54,727

Attachments:

- 1) Transmittal Sheet
- 2) Web page http://www.scicominc.com/porous_sheets.htm, Scientific Commodities, Inc., 2/15/2008 (3 sheets)
- 3) Web page <http://sciencelab.com/page/S/PVAR/60-136380018>, Science Lab.com, 2/15/2008 (1 sheet)

Porous Sheets



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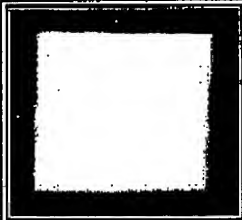
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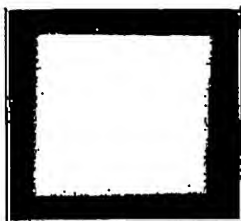
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| SCI Cat. # | Thickness | | Dimensions | | Sheet Type | Price | |
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| BB2061-125A | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$75.00 | Add to Cart |
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| BB2061-125AL | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$75.00 | Add to Cart |
| BB2061-125BL | 1/4" | 6.4mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$80.00 | Add to Cart |

POLYPROPYLENE 90 MICRON POROUS SHEETS

Porous Sheets



Polypropylene can operate safely at 210°F, or 230°F for a short period of time.

| SCI Cat. # | Thickness | | Dimensions | | Sheet Type | Price | |
|-------------|-----------|--------|------------|-------------|-------------|---------|-------------|
| BB2061-90 | 1/16" | 1.57mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$70.00 | Add to Cart |
| BB2061-90A | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$75.00 | Add to Cart |
| BB2061-90B | 1/4" | 6.4mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$80.00 | Add to Cart |
| BB2061-90L | 1/16" | 1.57mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$70.00 | Add to Cart |
| BB2061-90AL | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$75.00 | Add to Cart |
| BB2061-90BL | 1/4" | 6.4mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$80.00 | Add to Cart |



POLYETHYLENE 70 MICRON POROUS SHEETS

Polyethylene can operate safely at 210°F, or 230°F for a short period of time.

| SCI Cat. # | Thickness | | Dimensions | | Sheet Type | Price | |
|-------------|-----------|--------|------------|-------------|-------------|---------|-------------|
| BB2062-70 | 1/16" | 1.57mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$70.00 | Add to Cart |
| BB2062-70A | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$75.00 | Add to Cart |
| BB2062-70B | 1/4" | 6.4mm | 18" x 18" | 46mm x 46mm | Hydrophobic | \$80.00 | Add to Cart |
| BB2062-70L | 1/16" | 1.57mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$70.00 | Add to Cart |
| BB2062-70AL | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$75.00 | Add to Cart |
| BB2062-70BL | 1/4" | 6.4mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$80.00 | Add to Cart |



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| BB2062-35AL | 1/8" | 3.17mm | 18" x 18" | 46mm x 46mm | Hydrophilic | \$75.00 | Add to Cart |
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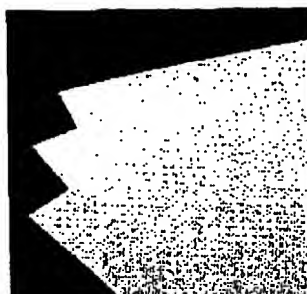
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| 60-136380018 | Fritware, Sheet, PE, Porous, Medium Grade, 36"X36"X1/8" | 1 | \$372.69 | 0 |
| 60-136380514 | Fritware, Sheet, PE, Porous, Medium Grade, 18"X18"X1/4" | 1 | \$135.60 | 0 |
| 60-136380518 | Fritware, Sheet, PE, Porous, Medium Grade, 18"X18"X1/8" | 1 | \$101.79 | 0 |
| 60-136385116 | Fritware, Sheet, PE, Porous, Medium Grade, 18"X18"X1/16" | 1 | \$67.89 | 0 |
| 60-136390518 | Fritware, Sheet, PE, Porous, Coarse Grade, 18"X18"X1/8" | 1 | \$101.79 | 0 |

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